REMARKS

This Response is to the non-final Office Action mailed on December 30, 2009. The Commissioner is hereby authorized to charge any fees that may be required or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 5828US BX2009T01740 (3712044-00440) on the account statement.

Claims 1 to 30 are pending in the application. Claims 31 to 65 were previously canceled. Claims 1, 13 and 24 have been amended by this Response. The amendments add no new matter and are supported in Applicants' specification, for example, at paragraphs [0094] to [0097], [0100] and FIGS. 4A and 4B.

In the Office Action, the specification was objected to for lacking antecedent basis. Claims 1 to 30 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 1, 2, 5 to 18, 20 and 22 to 30 were rejected under § 103(a) as unpatentable over U.S. Pat. No. 6,254,567 to Dennis Treu et al. ("*Treu*") in view of Roberts et al., "Innovative Peritoneal Dialysis Flow-Thru and Dialysate Regeneration" ("*Roberts*"). Claims 3, 4, 19 and 21 were rejected under 35 U.S.C. § 103(a) as unpatentable over *Roberts*.

Regarding the objection to the specification, the Office Action asserts that the specification lacks antecedent basis for the following cause and effect relationship recited in independent Claim 1, 13 and 24: the dialysate is drained from the fluid circuit at a discharge rate that is less than the circulation rate allowing, or effective to cause, the dialysate to be circulated a plurality of times along the fluid loop prior to discharge. See, Office Action, page 2.

Applicants first note that only Claim 1 recites draining fluid from a fluid circuit at a discharge rate less than a circulation rate. Claims 13 and 24 recite draining fluid circuit at a discharge rate effective to circulate the dialysate a plurality of times (Claim 24) or effective to cause the dialysate to circulate a plurality of times (Claim 13).

Applicants' moreover submit that the specification provides a clear antecedent basis pursuant to MPEP § 608.01(o) for the cause (i.e., maintaining discharge rate lower than circulation rate) and effect (i.e., dialysate circulating a plurality of times prior to discharge) relationship recited in the claims. Applicants' specification states, for example, that "the dialysate flow is controlled to cause the dialysate to circulate within the fluid loop a multiple number of times before discharge" (emphasis added). See, Applicants' US Publication No.

2004/0019320, paragraph [0097]. To control the dialysate flow to cause the dialysate to circulate multiple times within the fluid loop before discharge, "the feed rate and discharge rate of the dialysate into and out of the fluid loop 94 is maintained at an approximately equal rate that is less than the circulation rate of the dialysate in the fluid loop. In this regard, the multiple number of times that the dialysate is capable of circulation within the fluid loop 94 is approximately equal to the circulation rate divided by the feed rate or discharge rate" (emphasis added). See, Applicants' US Publication No. 2004/0019320, paragraph [0098]. The above passages provide a clear antecedent basis setting forth the claimed cause and effect relationship by establishing that (a) dialysate flow is controlled to cause dialysate to circulate multiple times prior to discharge (Claims 13 and 24) and (b) dialysate flow is controlled by maintaining discharge rate at a level less that circulation rate (Claim 1).

Applicants also respectfully submit that a person having ordinary skill in the art would recognize that by maintaining the discharge at a rate less than the circulation rate, dialysate circulating in the fluid loop would have to circulate more than a single loop before being drained via the discharge path because the dialysate has nowhere else to go. For example, if dialysate circulates through the fluid loop at a given flow rate, but discharges at half that flow rate, the dialysate would have to circulate twice on average before it is discharged. This is expressly confirmed in Applicants' US Publication No. 2004/0019320 in paragraph [0098]:

> For example, as illustrated in FIG. 4A, if the feed rate and the discharge rate equal about 50 ml/min and the circulation rate equals about 100 ml/min, the dialysate can circulate about two times into, through and out of the patient's peritoneum prior to discharge. It should be appreciated that the dialysate can be made to pass along the fluid loop any suitable multiple number of times that approximately equals the circulation rate divided by the feed rate or discharge rate.

Applicants respectfully submit therefore that, besides providing support in the specification for the claimed cause and effect relationship, one having ordinary skill in the art would recognize the cause-effect relationship between discharge/circulation flow rates and the number of times dialysate circulates a fluid loop. Applicants accordingly request that the objection to the specification be withdrawn.

Regarding the 35 U.S.C. § 112, first paragraph, rejection of Claims 1, 13 and 24, the Office Action rejects the same claim language as was at issue in the specification objection discussed previously, namely that dialysate is drained from the fluid circuit at a discharge rate

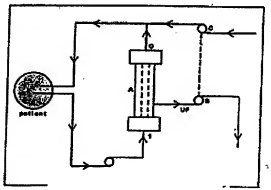
that is less than the circulation rate allowing, or effective to cause, the dialysate to be circulated a plurality of times along the fluid loop prior to discharge. The Office Action contends, in the §112 rejection, that the specification does not support circulating dialysate a plurality of times around a fluid loop as an express effect of discharging dialysate at a rate lower than the circulation rate. See, Office Action, pages 2 and 3.

Applicants respectfully disagree with the above assertions and submit that Applicants' specification provides support for circulating dialysate a plurality of times around a fluid loop as an express effect of discharging dialysate at a rate lower than the circulation rate. In summary of what was described previously with regard to the specification objection, Applicants' specification establishes that (a) dialysate flow is controlled to circulate dialysate multiple times prior to discharge (see, paragraph [0097] of the Applicants' US Publication No. 2004/0019320) and (b) dialysate flow is controlled by maintaining discharge rate at a level less that circulation rate (see, paragraph [0098]). Applicants also submit that a person having ordinary skill in the art would recognize that if dialysate circulates the fluid loop at a given flow rate (circulation rate), but discharge rate is maintained at half the circulation rate, dialysate would necessarily circulate twice before it is discharged.

Applicants respectfully submit therefore that Applicants' specification does support circulating dialysate a plurality of times around a fluid loop as an express effect of discharging dialysate at a rate lower than the circulation rate. Applicants accordingly request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claims 1, 2, 5 to 18, 20 and 22 to 30 are rejected under 35 U.S.C. § 103(a) as unpatentable in view of *Treu* and *Roberts*. In support of the obviousness rejection, the Office Action cited page 377, column 1, second paragraph of *Roberts*, which discusses an alternative flow-through method that involves the use of fresh dialysate for inflow, while fluid in the patient's peritoneum is recirculated at a high flow rate. No value for the *high* flow rate is specified in the cited paragraph, but the paragraph immediately preceding the cited paragraph discusses recirculation rates of 100 ml/min or 200 ml/min. The cited paragraph does however indicate that an inflow flow rate (feed rate of fresh fluid into the recirculation loop) can be 30 ml/min. *Most importantly*, the passage says, "the outflow of the spent peritoneal dialysate would be adjusted to the inflow." Applicants submit that this statement means that the outflow (discharge rate) is set to *match* the inflow (feed rate). As evidence, Applicants direct the Patent

Office to page 374, column 2, second paragraph (also cited in the Office Action) and Figure 7, reproduced below, of *Roberts* that shows a similar configuration to the peritoneal dialysis system described on page 377 except that the recirculation loop of Figure 7 has a hemofilter.



Regarding Figure 7, page 374 of *Roberts* discloses that the recirculating rate is set at 200 ml/min. The inflow (feed rate) and outflow (discharge rate) rates are *matched* or "adjusted" to be the same, i.e., to 36 ml/min. It should be appreciated that the spent dialysate outflow of both the cited passage at page 377 of *Roberts* and Figure 7 at page 374 of *Roberts* are analogous to the discharge fluid path of Claim 1. Since the feed and discharge rates are matched, the same amount of fluid introduced into the system must equal the amount of fluid discharging the system. Therefore the inflow rate into the patient and the outflow rate from the patient must also be equal to define a circulation rate.

Applicants accordingly respectfully submit that *Roberts* fails to disclose or suggest a fluid loop configured to circulate, or capable of circulating, dialysate into, through and out of a peritoneal cavity of the patient at an outflow rate from the peritoneal cavity greater than an inflow rate to the peritoneal cavity and a cycler configured to drain the dialysate from the fluid circuit at a discharge rate approximately equal, or at least substantially equal, to a difference between the outflow rate and the inflow rate as recited, in part, by present independent Claims 1 and 24. *Roberts*, by contrast, teaches a different flow regime as detailed above, namely, a balance of feed and discharge rates and a corresponding balance of inflow and outflow rates.

Roberts moreover fails to teach or suggest use of any hardware component that reads on the cycler device of Claims 1 and 24.

Regarding independent Claim 13, Applicants submit that *Treu* fails to disclose or suggest a fluid loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient via only a single loop of the fluid loop, the fluid loop including a first fluid line in communication with a dialysate supply, a second fluid line in communication with a discharge fluid path, a third line in communication with an outflow fluid path from the peritoneal cavity, and a fourth fluid line in communication with an inflow fluid path to the peritoneal cavity, wherein the discharge fluid path is coupled to the second and third fluid lines. The Office Action asserts that *Treu's* system 10 reads on the fluid loop of Claim 13. See, Office Action, page 6. Applicants submit, however, that system 10 in *Treu* fails to include the multiple fluid lines recited in Claim 13, namely fluid lines communicating with the dialysate supply, discharge fluid path, outflow fluid path and inflow fluid path. *Treu* therefore is deficient with respect to amended Claim 13. *Roberts* is not relied on to teach a fluid loop and is instead relied upon to disclose fluid drained at a discharge rate less than the circulation rate, which is text not included in Claim 13. Regardless, *Roberts* fails to teach anything related to the multi-line fluid loop of Claim 13.

The Office Action's "Response to Arguments" asserts again that Applicants' specification does not support the argument that Applicants' invention creates recirculation (i.e., circulation multiple times through the fluid loop) through a discharge rate that is lower that the circulation rate. See, Office Action, page 15. Applicants respectfully disagree for the reasons discussed above addressing the antecedent basis objection and §112 rejection.

The Office Action also contends that because Applicants disclose the same situation as *Roberts'* disclosure, it is therefore inherent that it is not solely Applicants' lower discharge rate that creates the higher circulation rate, but the addition of and the presence of a pump, just as *Roberts'* teaches. See, Office Action, page 16. Applicants respectfully disagree for at least the following reasons.

First, present independent Claims 1 and 24 do not recite the same situation as the *Roberts'* disclosure. Instead, Claims 1 and 24 recite a fluid loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient at an outflow rate from the peritoneal cavity greater than an inflow rate to the peritoneal cavity and a cycler configured to drain the

dialysate from the fluid circuit at a discharge rate approximately equal, or at least substantially equal, to a difference between the outflow rate and the inflow rate. As discussed above, *Roberts* teaches neither of these elements and instead teaches (a) equal outflow and inflow rates and (b) a discharge rate equal matched to a feed rate

Second, present independent Claim 13 does not recite the same situation as the *Roberts'* disclosure. Instead, Claim 13 recites a fluid loop including fluid lines communicating with the dialysate supply, discharge fluid path, outflow fluid path and inflow fluid path. As discussed above, *Roberts* does not teach the fluid loop of Claim 13 and is not even relied upon by Examiner for such a purpose.

For the foregoing reasons, Applicants submit that present Claims 1, 13 and 24 are allowable at this time, rendering any additional rejections of their respective dependent claims moot, and that all claims are accordingly in condition for allowance. If the Examiner believes that a telephone conversation would expedite prosecution in this case, or would be of use in understanding the above distinction over *Roberts*, Examiner is respectfully requested to call the undersigned.

Respectfully submitted,

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